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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/24/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,239

Applicant(s)

CHANG ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8, 9, 12-21, 30, 42-51, 53-62, 64-68 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 12, 21 and 30 is/are allowed.
- 6) ☒ Claim(s) 3, 8, 16-20, 46, 53 and 74 is/are rejected.
- 7) ☒ Claim(s) 2, 5, 6, 9, 13-15, 42-45, 47-52, 54-62, 64-68, 70-73 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. The finality of the previous Office Action is withdrawn due to a new ground rejection.

Status of the claims

2. Claims 2-6, 8, 9, 12-21, 30, 42-51, 53-62, 64-68 and 70-75 are pending.

Applicants' amendment filed December 30, 2002 (Paper No. 16) is acknowledged, and applicant's response has been fully considered. Claims 7, 10, 11 and 69 have been cancelled. Therefore, claims 2-6, 8, 9, 12-21, 30, 42-51, 53-62, 64-68 and 70-75 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 7, 10, 11 and 69 under 35 USC § 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at pages 1-2 in Paper No. 16.

Claim Rejections - 35 USC § 102

4. The previous rejection of claim 7 under 35 USC § 102(e), as being anticipated by Olson *et al.* (US 6,413,742), is withdrawn in view of applicant's cancellation of the claim in Paper No. 16.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "about 0 to 50 kDa" or "about 10 to 70 kDa", and the claim also recites "about 10 to 30 kDa", "about 30-50 kDa" or "about 50 to 70 kDa" which is the narrower statement of the range/limitation. See also claim 8.

Claim Rejections - 35 USC § 102

Note that patentability of the product by process resides in the product. Therefore, the product prepared by biochemical purification anticipates the same product produced by recombinant means. In the instant case, the human gelatin indicated in the reference is not distinguishable from the recombinant human gelatin of the claimed invention.

7. Claims 20, 46, 53 and 74 are rejected under 35 U.S.C. 102(b) as anticipated by Wironen *et al.* (U S 2002/0098222 A1, filed March 13, 1997).

Wironen *et al.* disclose a composition comprising a human gelatin in phosphate buffered saline solution (page 5, Table 1; claims 20, 46, 53 and 74).

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8. Claims 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerlach *et al.* (U. S. Patent 5,227,368).

Gerlach *et al.* teach an endotoxin-free gelatin (column 9, line 39; claims 16-19).

9. Claims 2, 5, 6, 9, 13-15, 42-45, 47-52, 54-62, 64-68, 70-73 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Claims 3, 8, 16-20, 46, 53 and 74 are rejected, claims 2, 5, 6, 9, 13-15, 42-52, 54-62, 64-68, 70-73 and 75 are objected, and it appears claims 4, 12, 21 and 30 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

March 20, 2003

Christopher S. F. Low
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